

Research and Development

The Use of Animals in DOD Programs

Summary. This regulation, as revised, has been retitled "The Use of Animals in DOD Programs." It creates uniform policies, procedures, and responsibilities among Department of Defense (DOD) components involved in the use of animals as outlined in this regulation. This regulation references pertinent Federal statutes and regulations and other standards related to the care and use of animals. It establishes policies regarding the care and use of animals. It also sets requirements for monitoring the care and use of animals whether performed by DOD personnel or contract or grant recipients. This regulation implements DOD Directive (DODD) 3216.1.

Applicability. This regulation applies to the active components of the military services. It also applies to Reserve Components engaged in activities involving the use of animals as defined in this regulation.

Impact on New Manning System. This regulation does not contain information that affects the New Manning System.

Supplementation. Army supplementation of this regulation is prohibited without prior approval of HQDA(DASG-RDZ),

WASH DC 20310. Send requests for exception, with justification, through command channels to HQDA(DASG-RDZ). Other DOD component supplements will be administered through the appropriate component offices listed in appendix A, according to individual component policies.

Interim changes. Interim changes to this regulation are not official unless they are authenticated by The Adjutant General. Users will destroy interim changes on their expiration date unless sooner superseded or rescinded.

Suggested improvements. The proponent agency of this regulation is the Office of The Surgeon General. Army users are invited to send comments and suggested improvements on DA Form 2028 (Recommended Changes to Publications and Blank Forms) directly to HQDA(SGRD-OP), Fort Detrick, MD 21701. Other DOD users should submit their comments and suggested improvements through the appropriate component offices listed in appendix A according to individual component policies.

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Clause 52.235-7003

Glossary

1. Purpose

This regulation sets policies, procedures, and responsibilities for using animals in DOD programs. As revised, this regulation covers transportation, care, use, review, reporting, and certain public affairs aspects for—

- a. Research, development, test, and evaluation (RDTE).
- b. Clinical investigation.
- c. Diagnostic purposes.
- d. Instructional programs or exhibitions in military departments and Defense agencies (DOD components).

2. References

Related publications are listed below. (A related publication is merely a source of additional information. The user does not have to read it to understand this regulation.)

- a. AFR 125-5 (USAF Military Working Dog (MWD) Program).
- b. AR 40-654 (Veterinary Services Nutritional Standards for Military Working Dogs).
- c. AR 40-905 (Veterinary Health Services).

*This regulation supersedes AR 70-18, 8 October 1976; SECNAVINST 3900.38A, 21 March 1977; AFR 169-2, 15 October 1982; DNAINST 3216.1B, 4 June 1982; and USUHSINST 3203, 17 December 1982.

d. AR 40-920/AFR 163-9 (Veterinary Laboratory Services).

e. AR 190-12 (Military Police Working Dogs).

f. AR 700-81/AFR 400-8/NAVINST 10570.1/MCO 105-0.1 (DOD Dog Program).

g. NIH 80-23 (Guide for the Care and Use of Laboratory Animals), Institute of Laboratory Animal Resources, National Resource Council. (This guide is available from the Division of Research Resources, National Institutes of Health, Bethesda, MD 20205.)

h. NIH 80-1520 (National Primate Plan), Interagency Research Animal Committee. (This plan is available from the Division of Research Resources, National Institutes of Health, Bethesda, MD 20205.)

i. SECNAVINST 3900.41 (Procurement, Transport, and Maintenance of Marine Mammals).

3. Explanation of abbreviations and terms

Abbreviations and special terms used in this regulation are explained in the glossary.

4. Responsibilities

a. The Under Secretary of Defense for Research and Engineering (USDR&E) will—

(1) Issue policies and procedural guidance under DODD 3216.1 concerning animal use.

(2) Allocate nonhuman primate resources to DOD agencies when their requirements exceed the number of animals available for DOD use.

(3) Designate a veterinarian as the DOD representative to the Interagency Research Animal Committee (IRAC). (This was formerly the Interagency Primate Steering Committee.) This person must have the proper rank or grade and experience. He or she must also be a diplomate of the American College of Laboratory Animal Medicine.

b. The Surgeons General of the Army, Navy, and Air Force; the Directors, Defense Advanced Research Projects Agency and Defense Nuclear Agency; and the President, Uniformed Services University of the Health Sciences will—

(1) Supervise the use of animals by their DOD components and implement this regulation.

(2) Establish a joint working group to identify and conserve nonhuman primate resources. The working group will be chaired by the DOD representative to the IRAC. This group will—

(a) Share primates and data.

(b) Transfer primates between DOD components.

(c) Establish primate breeding programs.

(3) Establish and provide representatives to a joint technical working group (JTWG). The JTWG will assist in the—

(a) Periodic review of the care and use of animals in DOD programs.

(b) Matters related to developing and issuing joint regulations implementing DODD 3216.1.

c. The Army Assistant Surgeon General for Research and Development (DASG-RDZ), as executive agent, will—

(1) Develop, with other DOD components, plans and procedures to insure adequate supplies of nonhuman primates and other species needed to meet DOD requirements. Plans will be sent to the USDR&E for approval.

(2) Develop and issue joint regulations to implement DODD 3216.1.

d. The Chief, US Army Veterinary Corps, will serve as consultant to the USDR&E for technical and professional matters concerning this regulation.

e. DOD component offices listed in appendix A will administer this regulation.

f. Local commanders will insure that—

(1) RDTE, clinical investigation, diagnostic procedures, or instructional programs are conducted in laboratories that conform to the standards and guidelines cited in this regulation. If there is conflict between the standards of humane care and use of animals, the most humane standards will be used.

(2) Local animal care and use, procurement, and transportation policies and procedures comply with this regulation.

(3) Animals used or intended to be used will experience no unnecessary pain, suffering, or stress, and their use will meet valid DOD requirements.

(4) Alternatives to animal species will be used if they produce scientifically satisfactory results.

(5) Dogs, cats, or nonhuman primates are not used in research conducted to develop nuclear, biological, or chemical weapons.

5. Accreditation

All DOD organizations having animals (other than military working, recreational, and ceremonial) will seek accreditation by the American Association for Accreditation of Laboratory Animal Care (AAALAC).

6. Statutes, regulations, and standards

a. The Laboratory Animal Welfare Act of 1966, as amended, and its implementing regulations require licensing of dealers, identification of animals, maintenance of records, submission of reports, and compliance with standards for the humane handling, care, treatment, and transportation of animals by dealers and research facilities (sections 2131-2156, title 7, United States Code (7 USC 2131-2156) and parts 1-4, title 9, Code of Federal Regulations (CFR 1-4)).

b. The Endangered Species Act of 1973, as amended,

and its implementing regulations provide a program, under the Department of the Interior, for conserving threatened and endangered species (16 USC 1531-1543) (50 CFR 10-14, 17, and 217-222). The Marine Mammal Protection Act of 1972, as amended, and its implementing regulations provide a similar program, under the National Oceanic and Atmospheric Administration, for marine mammals and marine mammal products (16 USC 1361-1384) (50 CFR 10-14, 18, and 216). These acts require the US Government to acquire permits, maintain records, make reports, and perform inspections on the care and handling of animals.

c. The Lacey Act prohibits the importation of certain wild animals or their eggs if the Secretary of the Interior determines that they are injurious to humans, the interests of agriculture, or other specified national interests. These wild animals and their eggs are identified within the Lacey Act documentation (18 USC 42) (50 CFR 16 and subpart B).

d. Regulations on the use of harmful or dangerous viruses, serums, toxins, and other similar agents in animals used in research facilities producing or testing biological products are presented in 21 USC 154 and 9 CFR 117.

e. Regulations on the import and export of animals, their shipment interstate and intrastate, and the requirements for their quarantine and inspection are presented in the following documents: 5 USC 301; 19 CFR 120; 21 USC 111-113, 114a, 115-117, 120-126, and 151-158; 9 CFR 71-97 and 122; 42 USC 216 and 264-272; and 42 CFR 71-72.

f. The Department of Health and Human Services provides additional guidance on housing, caring for, and using laboratory animals. Guidance is in NIH 80-23, "Guide for the Care and Use of Laboratory Animals."

g. The Department of Health and Human Services provides guidance on the supply and use of laboratory primates in NIH 80-1520, "National Primate Plan."

7. Animal use proposals

a. Proposals, whether conducted or sponsored by DOD components, that involve using animals will be written. They will include the following information:

- (1) Objectives.
- (2) Discussion of the need to perform the experiment, procedure, or demonstration.
- (3) Review or summary of the scientific literature or experience that led to the proposal.
- (4) Rationale for using the animal species and proposed numbers.
- (5) Design of the experiment, procedure, or demonstration.

b. The description of methods used in animal experiments, procedures, or demonstrations should be

complete and sufficient to indicate that pain and discomfort are minimized without compromising objectives of the experiment. Justification must be given for not using proper drugs when the procedures may cause pain or discomfort.

8. Animal care and use procedures

a. The local commanders of each DOD organization conducting or sponsoring activities involving animals in RDTE, clinical investigation, diagnostic procedures, or instructional programs will form a committee(s) to oversee the care and use of animals.

b. Committee(s) appointed by the local commander will be made up of at least three members. At least one person will not be involved in the proposed project and at least one member will be a veterinarian. Committee(s) will submit recommendations and be responsible to the local appointing official.

c. The committee(s) will—

(1) Periodically review all aspects of animal care to insure established policies, standards, and regulations are complied with.

(2) Review all protocols or proposals to insure that—

(a) The information sought by the use of animals is sufficiently important to warrant their use.

(b) The design of the experiment, procedure, or demonstration is adequate.

(c) The maximum amount of information consistent with good scientific research practice is obtained.

(d) The minimum number of animals needed for scientific validity is used.

(e) The model selected is the most suitable, based on consideration of the the experimental design, potential alternatives, and laboratory limits.

(f) The use of drugs to minimize pain or discomfort is adequate.

(g) Established policies on the use of animals are complied with.

d. Commanders responsible for working animals or recreational or ceremonial animals will regularly review and oversee their activities. The oversight will involve the local official attending veterinarian.

9. Centralized review of nonhuman primate use

a. Proposals involving the use of nonhuman primates will receive an additional centralized review by the proper DOD component office (app A). This review will conform with the criteria of NIH 80-1520. A centralized review will confirm that—

(1) The proposed research can be done only with nonhuman primates and that no other species or test system could produce comparable results.

(2) The species of nonhuman primates proposed for

use is the most suitable and that some more plentiful species would not be adequate.

(3) The number of nonhuman primates proposed is the minimum that will produce scientifically acceptable results.

(4) The nonhuman primates will not be euthanized during or at the end of the study except in cases requiring this as part of the investigation.

(5) If euthanasia is needed, positive action will be taken to share body material when feasible.

b. Each DOD organization using animals will establish review procedures and apply the criteria outlined in paragraph 6a and b. Protocols or proposals that involve using nonhuman primates must be reviewed and approved. The local DOD organization will send one copy of each protocol or proposal to the proper DOD office for centralized review.

10. Contracts and grants

a. RDTE, clinical investigation, diagnostic procedures, or instructional programs involving animals sponsored by a grant, award, loan, or contract from a DOD component will be conducted in facilities that conform to the standards and guidelines cited in this regulation. When conflict between the standards for humane care and use of animals exists, the most humane standards will be used.

b. Each DOD component sponsoring RDTE, clinical investigations, diagnostic procedures, or instructional programs involving animals will insure that the following criteria are met:

(1) Proposals or protocols are prepared according to paragraph 7 and reviewed using the criteria summarized in paragraph 8c and, where applicable, as outlined in paragraph 9.

(2) The care and use of animals are in compliance with prescribed standards and policies and that recipients of funds provide appropriate assurances of compliance. Assurances will include written statements from the recipient's animal care and use committee or other responsible official. Written statements will certify that the laboratories are accredited by AAALAC or that the care and use of animals will be done according to NIH 80-23 or other applicable Federal permits or regulations. The written assurances will also state that the protocol or proposal has been reviewed and approved by the local animal care and use committee or attending veterinarian. Site visits to assess animal care and use will be made as appropriate; the site visit team will include a person knowledgeable in laboratory animal science.

c. All contracts or grants by DOD that may involve using laboratory animals will contain clause 52.235-7003 of the DOD—Federal Acquisition Regulations Supplement (DOD—FAR) (app B).

11. Animal programs in foreign countries

To the extent that the local situation permits, research in foreign countries conducted by DOD personnel or sponsored by DOD funds will comply with the requirements of this regulation.

12. Use of DOD facilities

The use of animals jointly with or on behalf of other DOD, Federal, or civilian agencies in DOD facilities will comply fully with this regulation.

13. Release of information

a. If information about investigations using animals is released in a timely manner, public understanding and acceptance is likely to increase. This is especially so when it is shown that investigation results—

(1) Help solve military problems.

(2) Contribute to improved health and welfare of man and domestic animals.

b. Releasing information about an experiment involving animals before the experiment is completed should be the exception rather than the rule.

c. Material proposed for release to both the scientific community and the public will contain full information relevant to humane procedures used.

d. Publications describing the use of animals involving RDTE, clinical investigation, or instruction will include a statement of compliance with the Animal Welfare Act, when applicable. Publications should also include a statement declaring adherence to the principles enunciated in NIH 80-23.

e. Special attention must be devoted to insuring that all material (written, oral, and visual) will be acceptable to a wide audience, including lay as well as scientific readers, regarding specific techniques involving animals.

f. DOD components will develop public affairs policies, including the specific criteria mentioned in this paragraph. Local commanders will use these criteria when reviewing publishable written and presented materials involving animals.

14. Reports and inspections

a. DOD organizations do not register with the Secretary of Agriculture under the Animal Welfare Act but organizations holding or using animals subject to that Act are subject to inspection. Such organizations will submit reports to the US Department of Agriculture (USDA) as required by USDA regulations implementing the Animal Welfare Act.

b. All DOD organizations using animals subject to this regulation will submit copies of each USDA report, and other data as directed, to the proper office cited in appendix A.

Appendix A

DOD Component Offices

Assistant Surgeon General for Research and Development
Department of the Army
ATTN: DASG-RDZ
Washington, DC 20310

Commander
Aerospace Medical Division (AFSC)
ATTN: AMD/RD
Brooks Air Force Base, TX 78235

Commander
Naval Medical Command (MEDCOM-02E)
Washington, DC 20372

Director
Defense Advanced Research Projects Agency
ATTN: Administrative Office
1400 Wilson Boulevard
Arlington, VA 22209

Director
Defense Nuclear Agency
ATTN: OAMA
6801 Telegraph Road
Alexandria, VA 22310

President
Uniformed Services University of the Health Sciences
ATTN: ADO
4301 Jones Bridge Road
Bethesda, MD 20814

Appendix B

Department of Defense—Federal Acquisition Regulations Supplement

Clause 52.235-7003

Extracted from the DOD—Federal Acquisition Regulations Supplement

35.071(d) Care of Laboratory Animals. In compliance with law and in furtherance of the Department of Defense policy that all aspects of investigative programs involving the use of experimental or laboratory animals be humanely conducted in accordance with recognized principles, the following clause shall be included in all contracts awarded in the United States, its possessions, and Puerto Rico, which may involve the use of such animals.

52.235-7003 CARE OF LABORATORY ANIMALS (1974 APR)

(a) Before undertaking performance of any contract involving the use of laboratory animals, the Contractor shall register with the Secretary of Agriculture of the United States in accordance with Section 6, P.L. 89-544, Laboratory Animal Welfare Act, 24 August 1966 as amended by P.L. 91-579, Animal Welfare Act of 1970, 24 December 1970. The Contractor shall furnish evidence of such registration to the contracting officer.

(b) The Contractor shall acquire animals used in research and development programs from a dealer licensed by the Secretary of Agriculture or from exempted sources in accordance with the Public Laws enumerated in (a) above.

(c) In the care of any live animals used or intended for use in the performance of this contract, the Contractor shall adhere to the principles enunciated in the "Guide for Care and Use of Laboratory Animals" prepared by the Institute of Laboratory Animal Resources, National Academy of Sciences—National Research Council, and in the United States Department of Agriculture's regulations and standards issued under the Public Laws enumerated in (a) above. In the case of conflict between standards, the higher standard shall be used. Contractor reports on portions of the contract in which animals were used shall contain a certificate stating that the animals were cared for in accordance with the principles enunciated in the "Guide for Care and Use of Laboratory Animals" prepared by the Institute of Laboratory Animal Resources, NAS-NRC, and/or in the regulations and standards as promulgated by the Agricultural Research Service, USDA, pursuant to the Laboratory Animal Welfare Act of 24 August 1966, as amended (P.L. 89-544 and P.L. 91-579).

Note: The Contractor may request registration of his facility and a current listing of licensed dealers from the Regional Office of the Animal and Plant Health Inspection Service (APHIS), USDA, for the region in which his research facility is located. The location of the appropriate APHIS Regional Office as well as information concerning this program may be obtained by contacting the Senior Staff Officer, Animal Care Staff, USDA/APHIS, Federal Center Building, Hyattsville, Maryland, 20782.

(End of clause)

Glossary

Section I Abbreviations

AAALAC.. American Association for Accreditation of
Laboratory Animal Care
DAR Defense Acquisition Regulations
DOD Department of Defense
DODD..... Department of Defense directive
JTWG joint technical working group
RDTE research, development, test, and
evaluation
USDA US Department of Agriculture
USDR&E .. Under Secretary of Defense for Research
and Engineering
USUHS Uniformed Services University of the
Health Sciences

Section II Terms

Alternatives

Any system or method that covers one or more of the following:

- a. Replacing the use of laboratory animals altogether.
- b. Reducing the number of animals required.
- c. Refining an existing procedure or technique to minimize the level of stress endured by the animal.

Animal

Any living nonhuman vertebrate used for RDTE, clinical investigations, diagnostic procedures, and instructional programs or exhibitions.

Clinical investigation

All activities supported by clinical investigative funds.

Commander

Laboratory or unit commander, institute director, or other official having equivalent authority.

Dealer

Any person who, in commerce, for compensation or profit, delivers for transportation (or transports, except as a carrier), buys, sells, or negotiates the purchase or sale of animals.

Endangered species

A species or subspecies of mammal listed as "endangered" under the Endangered Species Act.

Exhibition

The use of animals, including working, recreational, or ceremonial animals, in displays, demonstrations, or ceremonies.

Injurious wildlife

Any wildlife for which a permit is required under the Lacey Act before being imported into or shipped between the continental United States and Alaska, Hawaii, the Commonwealth of Puerto Rico, or any possessions of the United States.

Instructional programs

All educational and training activities, except tactical training of personnel associated with military working dogs or other working, recreational, and ceremonial animals.

Marine mammal

Those species of the following orders, which are morphologically adapted to the marine environment, whether alive or dead, including but not limited to any raw, dressed, or dyed fur or skin: Cetacea (whales, dolphins, and porpoises) and Pinnipedia other than walrus (seals and sea lions).

Nonhuman primate

Any nonhuman member of the highest order of mammals, including prosimians, monkeys, and apes.

Research, development, test, and evaluation

All activities supported by RDTE funds.

Research facility

Any school (except an elementary or secondary school), institution, organization, or person that uses or intends to use live animals in research, tests, experiments, or instructional programs.

Threatened species

A species of mammal listed as "threatened" pursuant to the Endangered Species Act.

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Marine Corps: Marine Corps Lists H & I

Air Force: F

DARPA: Special

DNA: Special

USUHS: Special